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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,356	09/08/2003	Yu-Chin Lai	P03306	9555
23702	7590	10/24/2006		
Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701			EXAMINER MCCLENDON, SANZA L	
			ART UNIT	PAPER NUMBER

1711

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/657,356

Applicant(s)

LAI ET AL.

Examiner

Sanza L. McClendon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/03;3/05;1/06.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

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DETAILED ACTION***Election/Restrictions***

Applicant's election without traverse of invention of Group I, claims 1-19 in the reply filed on March 13, 2006 is acknowledged. The restriction requirement to the species, as described above, is acknowledged. However, with regard to said election of species, the examiner has withdrawn said election of species requirement, and, therefore claims under examination will now be claims 1-17 and 19 instead of 1-5, 7-8, 10-14, 16-17 and 19, as found in the reply filed June 8, 2006.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is unclear if applicant is intending for the "suitable material" to be a reaction product of the materials, as found in claim 1, such that the material comprises one or more blue-light absorption moieties and one or more light absorption moieties, and one or more photoinitiator moieties having absorption above 500 nm? Or, is applicant intending for the suitable material to be combined with a blue-light absorption compounds, one or more UV absorption compounds, and one or more photoinitiators having the claimed properties, such as in a reaction mixture and once reacted said suitable material has the blue-light absorber, UV-absorber and photoinitiator incorporated into the resin matrix of the medical device? Or, has applicant unintentionally omitted what is being incorporated into the suitable material, which comprises said claimed moieties? Clarification is requested.

For the advancement of prosecution, the examiner is interpreting the claims to be incorporating into a suitable material compounds having the desired claimed moieties, such as in a reaction mixture comprising a monomer/oligomer/resin/pre-polymer/polymer (as the suitable material) to which is added (in the reaction mixture) compounds having the instantly claimed properties.

Claim Rejections - 35 USC § 102/ Claim Rejections - 35 USC § 103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-10,12-13, 16-17 and 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over LeBoeuf et al (6,632,887 and 5,891,931).

LeBoeuf et al teaches methods of preparing foldable hydrophilic implantable ophthalmic lenses. Said method includes materials cured by exposure to blue-light using a benzoylphosphine oxide photoinitiator. Said lenses include one or more hydrophilic monomers, such as those found in columns 2-3. In addition, monomers other than the hydrophilic monomers can be included, such as those found in column 3, lines 35-41, wherein phenoxyalkyl (meth) acrylates are taught. These appear to anticipate at least some of those found in claims 7-10, especially claim 10. Other additives include UV-absorbing compounds, a blue-light blocking colorants both of which have been copolymerized with other (meth) acrylic compounds, and a one or more copolymerizable crosslinking monomers—see column 4. Said UV-absorbing compounds are found in column 4, lines 20-35, wherein at least one of these anticipates at least one of the UV-absorbers in claims 12-13. Said blue-light absorbing compounds are disclosed as being yellow dyes, such as those found in US 5,470,932; wherein said 5,470,932 teaches reactive azo-based

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yellow dyes having (meth) acrylic functionality. This appears to read on claim 5-6. Said crosslinkers are found in column 4, lines 36-55. Said composition is mixed, introduced into a mold of suitable shape and exposed to blue-light to cure and obtain said ophthalmic lens. Said exposure time for curing said molded composition is disclosed as being from 5 min. to 4 hours, preferably from about 15 min. to 2 hours—this anticipates claim 19.

The blue light can be obtained from sources such as those found in column 5. This teaching reads on claim 16. Regarding claim 17, it is not clear to the examiner if the disclosed light sources of LeBoeuf et al are xenon type lamp sources since they are disclosed by trade name/mark. In addition, since the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicant's irradiation sources differ and, if so, to what extent, from the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the applicant. However, in the alternative, applicant has not shown the criticality for using this type of lamp source (xenon) for patentability. Therefore the examiner deems that the composition, as instantly, claimed could be cured by exposure to any known visible light lamp sources and cure equally as well, in the absence of evidence to the contrary.

Regarding the limitation "photoinitiators having absorption above 500nm", it is not clear from the teachings of LeBoeuf et al if the phosphine-oxide photoinitiators have an absorption wavelength above 500 nm. However, LeBoeuf et al does teach that said phosphine oxide is initiated by exposure to blue-light and when used in conjunction with a blue-light absorption compound that the amount of initiator should be increased to minimize the interference with the light source. However, since the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicant's photoinitiators differ and, if so, to what extent, from the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

The invention of claims 1-10, 12-13, 16-17 and 19 are read in the reference.

6. Claims 1-12, 16-17, and 19 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over LeBoeuf et al (6,632,905 and 6,632,887).

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LeBoeuf et al teaches coatings for ophthalmic lenses. Said coatings include a curing a mixture of a hydrophobic polymer and hydrophilic polymer in the presence of a photoinitiator by exposure to blue-light radiation (visible light). Said hydrophobic polymer is obtained from a composition comprising one or more hydrophobic (meth) acrylate compound and a photoinitiators, optionally said composition can comprise a UV-absorbing compound, a blue-light blocking compound, and a chain transfer agent. Said UV-absorbers can be found in column 2, wherein benzotriazoles that anticipate at least one of those found in claim 12-13 can be found. Said blue-light blocker is incorporated by reference from US Pat. 5,470,932, which teaches (meth) acrylic containing azo-type yellow dyes. This is deemed to anticipate claims 5-6. Said hydrophobic monomers used in said composition can be found in column 2, see formula, wherein at least some of these anticipate the monomers of claims 7-10. Said photoinitiator is disclosed as being a phosphine oxide compound, which is taught to be a blue-light reactive photoinitiator.

The blue light can be obtained from sources such as those found in column 5. This teaching reads on claim 16. Regarding claim 17, it is not clear to the examiner is the disclosed light sources of LeBoeuf et al are xenon type lamp sources since they are disclosed by trade name/mark. In addition, since the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicant's irradiation sources differ and, if so, to what extent, from the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the applicant. However, in the alternative, applicant has not shown the criticality for using this type of lamp source (xenon) for patentability. Therefore the examiner deems that the composition, as instantly, claimed could be cured by exposure to any known visible light lamp sources and cure equally as well, in the absence to evidence to the contrary.

Regarding the limitation "photoinitiators having absorption above 500nm", it is not clear from the teachings of LeBoeuf et al if the phosphine-oxide photoinitiators have an absorption wavelength above 500 nm. However, LeBoeuf et al does teach that said phosphine oxide is initiated by exposure to blue-light and when used in conjunction with a blue-light absorption compound that the amount of initiator should be increased to minimize the inference with the light source. However, since the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicant's photoinitiators differs and, if so, to what extent, from the discussed reference. Therefore,

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with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

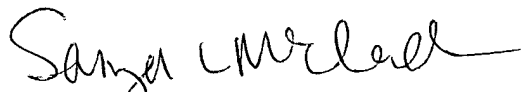
The invention of claims 1-10, 12-13, 16-17 and 19 are read in the reference.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sanza L. McClendon whose telephone number is (571) 272-1074. The examiner can normally be reached on Monday through Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Sanza L. McClendon

Examiner

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SMC